

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARRAY BIOPHARMA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 23-625-GBW
	)	
TEVA PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	
	)	

**OPENING BRIEF IN SUPPORT OF DEFENDANT'S MOTION TO STAY**

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**TABLE OF CONTENTS**

	<b>Page</b>
I. INTRODUCTION .....	1
II. BACKGROUND .....	2
III. LEGAL STANDARD.....	3
IV. ALL FACTORS FAVOR ENTERING A STAY HERE .....	4
V. CONCLUSION.....	7

## TABLE OF AUTHORITIES

	Page(s)
<b>Cases</b>	
<i>454 Life Scis. Corp. v. Ion Torrent Sys., Inc.</i> , No. CV 15-595-LPS, 2016 WL 6594083 (D. Del. Nov. 7, 2016) .....	5
<i>Array BioPharma, Inc. v. Alembic Pharmaceuticals Ltd.</i> , No. 22-cv-1277-GBW (D. Del.) .....	<i>passim</i>
<i>Choon's Design Inc. v. Tristar Prod., Inc.</i> , No. 14-10848, 2018 WL 11351661 (E.D. Mich. July 13, 2018) .....	5
<i>Cost Bros. v. Travelers Indem. Co.</i> , 760 F.2d 58 (3d Cir. 1985).....	4
<i>Ethicon LLC v. Intuitive Surgical, Inc.</i> , No. CV 17-871-LPS, 2019 WL 1276029 (D. Del. Mar. 20, 2019) .....	3
<i>NeoMagic Corp. v. Trident Microsystems, Inc.</i> , 287 F.3d 1062 (Fed. Cir. 2002).....	4
<i>Pers. Genomics Taiwan, Inc. v. Pac. Biosciences of California, Inc.</i> , No. CV 19-1810-GBW-MPT, 2022 WL 4245532 (D. Del. Sept. 15, 2022) .....	5
<i>RF Delaware, Inc. v. Pac. Keystone Techs., Inc.</i> , 326 F.3d 1255 (Fed. Cir. 2003).....	6
<i>SRI Int'l v. Matsushita Elec. Corp. of Am.</i> , 775 F.2d 1107 (Fed. Cir. 1985) (en banc).....	4
<i>UCB, Inc. v. Zydus Pharms. (USA) Inc.</i> , No. CV 16-903-LPS, 2017 WL 4310860 (D. Del. Sept. 28, 2017) .....	3, 5
<b>Statutes</b>	
21 U.S.C. § 355(b)(3)(C) .....	2

## I. INTRODUCTION

The Court should stay this case and administratively close it until the resolution of a related case. This Court has already construed the patents-in-suit in the related case, and the plaintiff, Array BioPharma, admits that under the Court’s construction, Teva does not infringe. Array seeks to move forward with a schedule for this case on the sole basis that it will seek to have the Court reconsider that claim construction decision. But such a parallel proceeding is inefficient. This Court has already decided the issue, and Teva is willing to be bound by that decision. The most efficient way to address this case is to stay it, and allow the dispute to play out in the related case, where it was previously briefed, argued, and decided.

Specifically, Teva respectfully requests that the Court stay this action pending resolution of any appeal of the Court’s Order and Memorandum Opinion construing the claim term “crystallized [binimetinib]” recited in the Crystallized Binimetinib Patents<sup>1</sup> in the related litigation, *Array BioPharma, Inc. v. Alembic Pharmaceuticals Ltd.*, No. 22-cv-1277-GBW (D. Del.) (“*Alembic*”). The Court invited Teva to file this formal motion to stay after Teva informally requested a stay in the parties’ joint status letter to the Court. *See* D.I. 15 at 2; D.I. 16. As Array admits, the Court’s construction of “crystallized [binimetinib]” in *Alembic* disposed of *all* Array’s claims against Teva in this litigation. Thus, staying this litigation at this very early stage—before even a scheduling order has been entered—would conserve the Court’s and the parties’ resources without causing any undue prejudice to Array. Teva respectfully requests that the Court grant Teva’s motion and stay this litigation pending resolution of any appeal of the claim construction decision in *Alembic*.

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<sup>1</sup> The asserted patents in this case are U.S. Patent Nos. 9,562,016, 9,598,376, and 9,980,944 (collectively, the “Crystallized Binimetinib Patents”).

## II. BACKGROUND

On August 8, 2022, Teva provided Array notice that Teva sought to market its proposed generic binimetinib product before the expiration of the Crystallized Binimetinib Patents. D.I. 1 ¶ 24. Teva does not seek to bring its proposed ANDA product to market before the expiration of a different set of Orange Book-listed patents, expected to expire in 2030 or later—referred to in *Alembic* as the “Huang Patents.”<sup>2</sup> In contrast, Alembic and Sandoz filed Paragraph IV certifications on the Huang Patents as well as the Crystallized Binimetinib Patents, and Array sued them in 2022. *See Alembic*, D.I. 1 ¶¶ 1, 40; *Array BioPharma, Inc. v. Sandoz, Inc.*, No. 22-cv-1316-GBW, D.I. 1 ¶¶ 1, 35; *Alembic*, Minute Order Dec. 22, 2022 (consolidating Alembic and Sandoz cases).

Nearly a year after receiving Teva’s notice letter, on June 8, 2023, Array filed a complaint against Teva, alleging that Teva’s proposed generic binimetinib product would infringe the Crystallized Binimetinib Patents. D.I. 1 ¶¶ 1, 24. No thirty-month stay governs this action because Array’s suit was filed more than 45 days after Teva notified Array that Teva had submitted its Abbreviated New Drug Application (“ANDA”) to FDA seeking approval to sell its proposed generic binimetinib before the expiration of the Crystallized Binimetinib Patents. *Id.* ¶ 24; *see* 21 U.S.C. § 355(b)(3)(C). Teva filed its answer and counterclaims to Array’s complaint on August 4, 2023; Array answered Teva’s counterclaims on August 24, 2023. D.I. 10; D.I. 12.

After these initial pleadings were filed, Array showed little interest in prosecuting the case. Instead, Array proceeded to claim construction in *Alembic*. The Court entered a construction of the claim term “crystallized [binimetinib]”: “binimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol.” *Alembic*, D.I. 93 at 11; *Alembic*, D.I.

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<sup>2</sup> The Huang Patents are U.S. Patent Nos. 9,314,464, 9,850,229, and 10,005,761.

94 at 3. Array then stipulated that under the Court’s construction, Alembic and Sandoz did not infringe the Crystallized Binimetinib Patents. *Alembic*, D.I. 131; *Alembic*, Minute Order May 24, 2024; *Alembic*, D.I. 133; *Alembic*, D.I. 134.

Array continued to neglect this case until the Court ordered the parties to meet and confer regarding a scheduling order after more than a year had passed since Array filed its complaint. D.I. 13. After meeting and conferring, the parties submitted a joint letter in which “Array acknowledge[d] that Teva does not infringe the Crystallized Binimetinib Patents under the Court’s claim construction in the *Alembic*/Sandoz litigation.” D.I. 15 at 1. Despite its concession of Teva’s non-infringement, Array urged the Court to allow this litigation to proceed so that Array can argue that the Court’s claim construction in the *Alembic* case is incorrect. *Id.* at 1–2. Teva, on the other hand, requested that the Court exercise its inherent power to stay this case pending any appeal of the Court’s claim construction in *Alembic*, and agreed to be bound by any appeal of the claim construction decision in *Alembic*. *Id.* at 2–3. After reviewing the parties’ letter, the Court invited a stipulation regarding a stay, or else, a formal motion seeking a stay. D.I. 16. Teva reached out to Array and proposed that the parties stipulate to a stay pending appeal in *Alembic*. Array again refused to stipulate to a stay, insisting it should have an opportunity to revisit the *Alembic* claim construction. Teva thus now brings the motion to stay invited by the Court.

### III. LEGAL STANDARD

Courts consider three factors in determining whether to stay a case: whether a stay will simplify the issues for trial, whether discovery is complete and a trial date has been set, and whether a stay would unduly prejudice the non-moving party. *UCB, Inc. v. Zydus Pharms. (USA) Inc.*, No. CV 16-903-LPS, 2017 WL 4310860, at \*1 (D. Del. Sept. 28, 2017); *Ethicon LLC v. Intuitive Surgical, Inc.*, No. CV 17-871-LPS, 2019 WL 1276029, at \*1 (D. Del. Mar. 20, 2019). The Third Circuit has held that the grant of a motion to stay “is committed to the district court’s

discretion, since it is a matter of the court’s inherent power to conserve judicial resources by controlling its own docket.” *Cost Bros. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985).

Each of these factors supports staying this case.

#### IV. ALL FACTORS FAVOR ENTERING A STAY HERE

The Court should stay this litigation. Array concedes that the claim construction adopted by this Court in *Alembic* resolves the question of infringement of the only three patents at issue here (the Crystallized Binimetinib Patents). Staying this case at this early stage, before discovery has even begun, is an efficient use of judicial resources. And there is no prejudice to Array—Array has shown no interest in moving this litigation forward and there is no thirty-month stay on FDA approval. All three legal factors strongly favor granting a stay.

A stay clearly simplifies the issues. Array has admitted that it currently has no basis to proceed with its infringement claims against Teva. Array’s only argument for doing so is based on its desire for a second bite at the apple—“revisiting the Court’s claim construction of the crystallized binimetinib term in this case” and “ask[ing] the Court to reconsider the claim construction issue in this case.” D.I. 15 at 2. But allowing Array to “revisit” in this case the Court’s claim construction order from *Alembic* would be inefficient. Moreover, “[i]t is well settled that claims may not be construed by reference to the accused device.” *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (citing *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc)). Regardless, nothing about the *Alembic* claim construction is specific to the facts there, and there is no reasonable basis to suggest that the Court would reach a different conclusion in this substantially similar matter under the same patents. Additionally, as Teva has already indicated (*see* D.I. 15), Teva is willing to agree to be bound not just by this Court’s claim construction already entered in *Alembic*, but also by the final resolution of the claim construction upon any subsequent appeal. Thus, staying the case now—

especially given that Array has conceded it has no substantive case to bring under the construction that this Court has already adopted—provides a fair, efficient outcome.

Under similar circumstances, this Court has held that “[j]udicial efficiencies would be gained by staying this case rather than have this Court and the Federal Circuit address the construction of the same term in parallel.” *Pers. Genomics Taiwan, Inc. v. Pac. Biosciences of California, Inc.*, No. CV 19-1810-GBW-MPT, 2022 WL 4245532, at \*2 (D. Del. Sept. 15, 2022). Other courts, both in this District and elsewhere, have likewise found that resolution of a parallel appeal simplified the issues on comparable facts. *UCB*, 2017 WL 4310860, at \*2 (first factor weighed in favor of a stay where validity of all asserted claims would be decided in related appeal); *see also Choon’s Design Inc. v. Tristar Prod., Inc.*, No. 14-10848, 2018 WL 11351661, at \*2 (E.D. Mich. July 13, 2018) (stay pending appeal of claim construction decision in related action simplified infringement issue; stay granted). If a stay were granted, there would be no need for a trial, discovery, or any other litigation activity unless and until an appeal of the Court’s claim construction order in *Alembic* results in a reversal of this Court’s construction of the “crystallized [binimetinib]” term. Therefore, the simplification-of-issues factor favors granting the stay.

The early stage of this case also favors a stay. Although Array filed its complaint in June 2023, this case is still materially “in its infancy.” *UCB*, 2017 WL 4310860, at \*2. “Granting a stay relatively early in a case can be said to advance judicial efficiency and maximize the likelihood that neither the Court nor the parties expend their assets addressing invalid claims” or claims that are not infringed. *454 Life Scis. Corp. v. Ion Torrent Sys., Inc.*, No. CV 15-595-LPS, 2016 WL 6594083, at \*4 (D. Del. Nov. 7, 2016) (quotation marks and alterations omitted). This Court has previously stayed cases that were in much later stages of litigation. *See, e.g., Pers. Genomics*, 2022 WL 4245532, at \*2 (staying case after claim construction briefing was complete). Here, the



parties' only substantive exchange has been the recent discussion regarding the case schedule. A stay would not waste already-expended resources by the parties because the parties have expended relatively little thus far. Instead, a stay would prevent the parties from wasting resources by re-litigating a claim construction issue that has already been decided by the Court.

Finally, Array has no basis to argue that it would be prejudiced, much less unduly prejudiced, by a stay. Rather than pushing this case toward resolution or entertaining Teva's requests for settlement discussions, Array let the case idle for a full year. During that time, Array litigated the relevant claim construction issue in *Alembic*. Array lost. As Array admitted, that decision is dispositive here. Array's only argument to the contrary rests on *RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1261 (Fed. Cir. 2003), which held that collateral estoppel does not attach to non-final claim construction orders. That argument is a *non-sequitur*. First, *RF Delaware* did not involve a judge revisiting and reversing in one case the judge's own claim construction in a related case. Teva does not dispute that the Court has the ability to do that here, but this would be inefficient. Second, Teva does not request dismissal based on collateral estoppel, and a stay would not deprive Array of the opportunity to argue infringement against Teva if Array obtains reversal of this Court's construction. Indeed, Teva has already offered to be bound by the resolution of any appeal of the claim construction issues in *Alembic*. D.I. 15 at 3. Instead, a stay would merely prevent Array forcing Teva to engage in duplicative litigation of an already-decided issue, saving the Court from wasting resources resolving a dispute that it has already resolved.

It is true that a stay would delay final resolution in this case, but such delay would work no prejudice, let alone undue prejudice. Teva has not sought to bring its proposed ANDA product to market before the expiration of the Huang patents, which are not expected to expire until the year

2030 or later. Even if the Federal Circuit were to overturn this Court's claim construction on appeal, Array could expect to fully litigate its case against Teva long before Teva would be permitted to launch its proposed ANDA product. At any point, including right now, Array could also discuss amicable resolution of this action with Teva. Array has offered no evidence, or even argument, of any prejudice.

## V. CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court stay this action pending resolution of any appeal of the Court's claim construction order in the related *Alembic* litigation.

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